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JAT MRO, Inc.
MEDICAL REVIEW OFFICER SERVICE

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DEPARTMENT OF TRANSPORTATION
400 7TH ST, SW
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WASHINGTON, DC 20590

Dear Sir/Madam:

I have the following comments concerning the Notice of Proposed Rulemaking (NOPR) to revise 49 CFR Part 40:

s40.11 (e) and **(f):** Many employers, particularly smaller ones, do not enter into formal written agreements with Medical Review Officers (MROs), therefore these provisions are appropriate and apt in many cases, and should be retained to accommodate this common situation. However, it may be burdensome for certain employers to obtain and retain these written statements, particularly when an MRO is used for the first, and perhaps only time, e.g. in a post-accident setting where the employer uses a clinic to treat and drug-test the employee after an accident. In such cases the employer, in the interest of obtaining a drug test in a timely fashion may use an MRO recommended by the clinic for that particular case, using Custody and Control Forms (CCFs) obtained by the clinic but modified to show the actual employer's name, address, and telephone number. In such an instance the provision of such a statement to the employer would perforce occur after the collection of the specimen. From the MRO's standpoint, providing such a statement to each employer as they begin providing services, or, for existing accounts at some point after the adoption of these provisions, is certainly feasible, but burdensome, particularly if the MRO has many small employers who occasionally do DOT testing. I would suggest that consideration be given to establishing a central registry of MROs, maintained by DOT ODACP, who have provided this statement to DOT, so that employers need only consult this registry to insure that any MRO they use has stipulated in writing to providing services in compliance with 49 CFR Part 40. This MRO registry might also contain additional information and serve other purposes.

s40.33: I feel the requirements in this section that the collector be trained by another person "sufficiently knowledgeable . . . " too vague, and prone to misunderstanding, misapplication, and will result in a very wide range of competence among people collecting urine specimens under this rule. This is the situation now, and poorly trained, incompetent collectors do provide a very large source of errors, time and money wasted in the testing process. I suggest that formal training, and retraining be required, i.e. a formal course with a certification requirement, analogous to the requirements for training of Breath Alcohol Technicians (BATs). Although cumbersome at first, I think that provided a sufficiently long grace period is provided, for e.g. within 2 years of the implementation of the rule, to allow development and

certification of training programs, and then to complete initial training of collectors, this provision will provide great long-term benefits for the drug testing program. However, for certain special circumstances, i.e. post-accident, and reasonable suspicion, where it can be established that a certified collector could not be located in a timely enough fashion to provide for the prompt collection that is vital for these types of testing, that uncertified collectors be permitted to be used In these special instances, the collector should be required to be a medical professional .

s40.45(b): Permitting the printing of CCFs with white pages with specified colored borders for each page is entirely appropriate and should be retained. This bears on a major problem posed by CCFs. Many MROs currently rely on the faxed Copy 4 or its equivalent to insure rapid review and reporting of accurate results, in accordance with current Federal requirements. Many CCFs (and particularly the Copy 4, 5, 6 or 7, of those CCFs) do not fax well, and are often completely or partially illegible, so as to render them useless in verifying results, despite the efforts of collectors to fax them to the MRO promptly. Allowing use of colored borders would eliminate some of these problems by permitting better fax transmission. However, many CCFs are printed with very small letters and numbers, that are often too faint to read on the original Copy 4, 5, 6, or 7, to say nothing of the faxed Copy. This section should require that all printed portions of the CCF be clearly legible on all copies, both in the original and when faxed.

s40.47(b): This section requires that the MRO obtain a signed statement from the collector stating the reason why a non-Federal CCF was used for a DOT collection. It does not state whether this must be accomplished before verifying the result, although it does indicate that this is not a reason for the MRO to cancel the result. In many instances employers perform urine drug testing for employees who are covered under Federal regulations as well as for those who are not. These employers maintain two sets of CCFs, one for each type of testing. They often rely on local supervisors, or collection agencies, to issue the appropriate form at the time of testing. Needless to say, this process is often confusing, and a non-Federal form is used for DOT testing and vice-versa. The MRO usually has no way of knowing whether any given test was for a covered employee or not, and therefore whether or not the appropriate CCF was used in any given case. In my practice, I accept the CCF on face value assuming the employer has correctly issued the type of CCF appropriate to the type of test being conducted. In reporting the results we have different reporting formats so that the employer knows which CCF was used for any given test (i.e., our non-Federal report form is clearly distinguishable from our Federal report form). I suggest that it is the employer's responsibility in the first place to correctly issue a CCF appropriate for the type of testing conducted in each case. The circumstance of post-accident testing described in this section is quite rare and probably could be handled by the MRO ad hoc. However, it is far more common for employers to have large scale programs of random, pre-employment or other testing for both covered and uncovered employees that result in a much greater frequency of an inappropriately used CCF. It would be extremely difficult and burdensome, and certainly impracticable if not impossible, for the MRO to know which CCF should have been used for any given collection, and then chase down these statements in such cases. If this requirement is to be retained it is suggested that the employer be required to obtain this statement from the collector and retain it in their files as soon as it becomes apparent to the employer upon receipt of the report of the results from the MRO that an inappropriate CCF has been used. If necessary, the employer could call upon the MRO or the laboratory to assist him in locating the collector so that this can be accomplished, but it should remain an employer responsibility; they are responsible for the overall integrity of the program, including selection of competent, responsible, collection agencies.

s40.65(b): It appears that the requirement that the donor is to be asked to give an oral temperature before deciding whether or not an observed collection is to be obtained for temperature out of range specimens has been omitted from the proposed rule. If this was intentional I agree with its omission. This is a cumbersome and contentious procedure, often ignored by collectors, and rarely useful, except in the very unusual cases where the donor has a high fever and presents a urine that is warmer than 100 degrees F, or there is a defective temperature strip for a urine that is warm to the touch and would be temperature in range were the strip working properly. Given the rarity of these two instances, I feel it is appropriate to

eliminate the requirement for oral temperature testing, and simply proceed to a directly observed specimen in temperature out of range situations.

s40.75(a)(1): This section properly requires the collector to note in the "Remarks" section of the CCF when an employee refuses to sign the donor certification statement. Although it seems obvious, in the interest of insuring no misunderstanding on this point, the section should state that the specimen is still to be submitted despite the refusal of the donor to sign the CCF. There are some other circumstances that occur from time to time that should be addressed here as well. In some cases the donor, though conscious, and capable of providing a urine specimen, is physically unable to sign the donor certification statement (e.g. broken arms, burnt hands, etc.). In these instances the collector should be required to note in the "Remarks" section that the Donor was physically unable to sign the statement, but acknowledged that this was the donor's specimen and it was sealed in the donor's presence, etc. Similarly, in other cases the donor does not know how to sign his/her name and must make a mark. In this case the collector should be required to state in the "Remarks" section the donor's name and that the mark was used as the signature. Finally, some donors do not read or even speak English, but sign the donor certification statement on an English language form. In the situation where the collector knows that the donor does not read or speak English, and an English language form was used, it should be required that the collector note in the "Remarks" section that the donor certification section was explained to the donor and the donor understood and acknowledged that this was donor's specimen and it was sealed in the donor's presence, etc. Similarly, I feel that employers in the U.S. should be permitted to use foreign language CCFs for Donors who do not speak English even when the testing is conducted in the U.S. I don't feel it is necessary for the Collector to speak or read the language on the form so long as they understand (i.e. through prior training) what the CCF states, and can ensure that the Donor understands what he is signing, etc.

s40.89(a): This section should require tests confirmed as positive for Methamphetamine automatically undergo chiral (i.e. isomerization) assay and be reported in terms of the percentage of D and L Methamphetamine present. Good MRO practice requires that donor use of over-the-counter (OTC) preparations that might produce a great preponderance of L-Methamphetamine (i.e., greater than 80%) be ruled out before verifying as positive a test confirmed as positive for Methamphetamine by the laboratory. Many donors with Methamphetamine confirmed positive results offer use of such an OTC preparation as an explanation, and even for those who do not volunteer or recall such use, it is imperative that this be ruled out before proceeding to verification. Without the requirement for automatic chiral assay, much time, often as much as 5 or more working days, is wasted while waiting for the results of the chiral assay if it is ordered at the time the MRO receives the result from the laboratory, and even more is wasted if the MRO waits until after conducting the interview to order the analysis. Some of this delay is due to the fact that currently not all laboratories certified to perform Federal testing have the capability to perform chiral analysis in house and must send the sample out in order to provide the analysis to the MRO. Some have suggested that the MRO simply file a blanket request with all laboratories that all results confirmed positive for Methamphetamine for any account that MRO handles undergo chiral assay. However, others, including some Laboratory Directors, have stated that this is not permissible under current guidelines, and that the only blanket request of this sort that may be made concerns the quantification of opiate results. Many employers may be reluctant to pay the additional fee most laboratories charge for chiral analysis on an automatic basis, preferring the MRO to conduct his interview before ordering the chiral analysis, despite the great loss of time in coming to a final verification this often poses. I feel this is highly analogous to the requirement that 6-acetylmorphine assays be automatically performed for results confirmed as positive for morphine, and is as necessary and valuable, as this very worthy addition to current Federal requirements for urine toxicological testing. In the interest of rapid, appropriate, and equitable verification of Methamphetamine positive results, automatic chiral analysis and reporting of results in terms of the percentage of D and L Methamphetamine present should be required in this rule.

s40.93(d)(1): There are two typographical in this section on my copy of the proposed rule. At one point is states the specimen is adulterated if the nitrite concentration is <=500 MUg/mL, obviously what is meant

here is >=500 MUg/mL. Similarly it states the specimen is adulterated if the pH is <= 11, what is obviously meant here is >= 11.

s40.101: I agree with this section as written in toto, and it should be retained without further modification.

s40.103(a): I think it entirely appropriate that employers, etc., with less than 2000 DOT-covered employees be no longer required to submit blind quality control specimens. This requirement for smaller entities is extremely burdensome, often not understood by smaller operators and unnecessary, given the large volume of blind quality control testing already being performed by larger operators.

s40.127(a)(2): The requirement the MRO personally review and initial at least 10% of the CCFs reviewed by the MRO's staff on a quarterly basis is excessive and unnecessary. For quality control purposes, far fewer than 10% of any sample of anything is considered adequate, e.g., the number of blind quality control specimens equal to 1% of urine toxicological specimens collected by employers annually that are required to be submitted in this proposed rule. It is suggested that this requirement be modified to 1% of the CCFS reviewed by the MRO's staff on a quarterly basis.

s40.127(b): I heartily endorse this entire section. It is entirely appropriate that a legible copy or the original of Copy 2 of the CCF and /or a laboratory results report and a legible copy or the original of any copy of the CCF containing the donor's signature be sufficient to verify and report negative results.

s40.127(d): It is unclear as to whether a staff member can sign or initial the Copy 4 of the CCF for a negative result, in lieu of the MRO's own signature or the MRO's signature stamp. It would seem to me that if the MRO is required to review for quality control purposes and initial some percentage of the CCFs reviewed by his staff, it is imperative that the MRO and any auditor be able to tell just which staff member performed the review. Therefore, in all cases, the staff member performing the review should be required to initial the CCFs reviewed by that staff member. In situations where the Copy 4 is not used as the report form to the employer, all that should be necessary is an indication that the test is reviewed as negative, the date of the review and the reviewer's initials in the verification statement. Of course, where the Copy 4 is used to report negative results, the MRO's own signature, or the MRO's signature stamp, and the printed name of the MRO should also appear in the verification statement.

s40.129(b): I heartily endorse this entire section. It is entirely appropriate that a legible copy or the original of Copy 2 of the CCF and a legible copy or the original of any copy of the CCF containing the donor's signature be sufficient to verify and report positive results.

s40.129(d): I recommend that alternative 1 for this paragraph be retained in the rule. I think it unwise to give any impression to the DER or other persons that a test may be verified as positive until that is in fact accomplished. Too many employers will misunderstand and misapply any indication from the MRO that the result was confirmed as positive by the laboratory and will take inappropriate actions and apply uncalled for sanctions in advance of the MRO's final determination. Given that a number of laboratory confirmed positive results will ultimately be verified as negative, and some will also be canceled by the MRO, the possibility that unfair or inappropriate sanctions will be applied is too great to permit alternative 2 to be adopted.

s40.131: I agree with this section as written in toto, and it should be retained without further modification. I particularly endorse subparagraph (b); the requirements for the MRO to speak with the Donor personally, and the limitations on the role of the MRO's staff set out here are entirely appropriate and should be retained.

s40.133(a): I note that this section allows verification a test result is positive if the Donor fails to contact the MRO more than 72 hours after the DER has documented contact with the Donor. This is a change from the current rule that requires 5 days to elapse before verification can be made in these circumstances. I feel that 5 calendar days should be retained. Given weekends and holidays this seems a fair interval. To avoid confusion I think calendar days rather than working days should be used whenever time frames are outlined in this rule. The requirement that the MRO wait until 14 days have elapsed from when the confirmed positive result was received to verify the result as positive when neither the DER nor the MRO can contact the Donor is over long. It is suggested that a period of 7 days (calendar days) is a fair interval in this circumstance.

s40.137: For results confirmed by the laboratory as positive for PCP, I feel that so long as MRO is in possession of the original or a copy of the Copy 2, and the original or a copy of the Copy 4 or any copy of the CCF containing the Donor's signature, they should be permitted to be verified as positive by the MRO. This is different than the requirements for marijuana, cocaine and amphetamines outlined in this section, and should be so. There is no legitimate medical explanation that can be provided by the Donor for a positive result for PCP. Therefore requiring the same process here as for the other drugs is pointless and a waste of time.

s40.139: I agree with this section as written in toto, and it should be retained without further modification. I especially feel that subparagraph (b) is entirely appropriate and should be retained. I also especially feel that subparagraph (c), and especially sections (iii) and (iv), should be retained without modification.

s40.141: I agree with this section as written in toto, and it should be retained without further modification.

s40.143: I agree with this section as written in toto, and it should be retained without further modification.

s40.147: I agree with this section as written in toto, and it should be retained without further modification. I do not feel that a re-test under direct observation should be required for negative dilute specimens. There are a great many innocuous situations in which the Donor drinks quantities of fluids sufficient to produce a dilute urine (including being urged by the employer or collector to do so prior to collection!) without any intent of frustrating the testing process. Because of these frequent innocent situations, often in response to legitimate health and wellness concerns on the part of the donor (and it is not illegal, immoral or politically incorrect to drink plenty of fluids) requiring a re-test, or permitting the employer to have the discretion to disregard a negative dilute result should not be authorized in this rule.

s40.153: I agree with this section as written in toto, and it should be retained without further modification. Split specimen testing should not be permitted when the specimen has been substituted or adulterated. The fact that these situations are highly analogous to other circumstances where the Donor deliberately attempts to frustrate the testing process (e.g. leaving the collection site without providing a specimen at all), that many of the adulterants may rapidly degrade over time, and that a requirement for split specimen testing may lead to even more sophisticated attempts to adulterate specimens, amply support not permitting split specimen testing here. However, given the extreme sanctions applied to a Donor with a verified canceled result due to adulteration or substitution, care must be taken that the criteria for the laboratory's finding that a specimen is adulterated or substituted is scientifically defensible and equitable. In this regard I think that unless further evidence can be produced that urines with creatinine levels less than or equal to 5 are in fact not representative of human urine that this level should be reduced. In my own experience I have encountered a situation where a Donor has had urine creatinine levels of between 4 and 5, where I believe that the urine was not in fact substituted and was produced by that Donor. It seems to me that this level should be reduced somewhat, perhaps to the level of detection

for creatinine for the method used by the laboratory when measuring this, until that level of urine creatinine that is actually not consistent with human urine in all cases can be established.

s40.155(a): Subparagraph (1) of this section requires the MRO to rule out collector error in cases where specimens are rejected for testing by the laboratory and states that the MRO must consult with the collection site in making this determination. This procedure is cumbersome, burdensome, and unnecessary in most cases. For many situations it is obvious that it is collector error that is responsible by the nature of the error causing the specimen to be rejected, e.g., the "fatal flaws" delineated in s40.197(a), (b) and (d) of the proposed rule, among others. To require the MRO to consult with the collection site every time one of these errors occurs will result in a huge and needless waste of time. It is strongly suggested that this section be modified to state that the MRO may consult with the collection site in making this determination.

s40.157(d): Electronic signatures should be permitted on reports of negative test results. This is really no different than allowing a staff member to rubber-stamp such a report. So long as there is some indication on the CCF (i.e., the staff members' initials) as to which staff member reviewed the result, I feel that permitting this will only enhance the prompt reporting of results without any real drawbacks. However, for positive and canceled results, I feel that requirement for the MRO to sign the report is vital and must be retained. To insure that it is in fact the MRO, and not a surrogate who is making the final determination in these instances, this requirement should be retained.

s40.159(a): I feel alternative 1 should be retained. The medical stand-down policy provided for in alternative 2 is inappropriate in that in too many cases it will be misunderstood and misapplied resulting in unfair, uncalled for, burdensome and unnecessary sanctions for donors who ultimately will have results verified as negative or canceled. Such a policy also undermines the confidentiality of the MRO verification process by planting a seed in the minds of employers that there is some medical condition or circumstance that the donor is suffering that they should know about, even when they should not as provided for in other parts of this rule. This may lead to inappropriate actions on the part of employers to ferret out this information even though they have no right to it, leading to unfortunate situations that would violate the letter and spirit of this regulation as well as others. I feel that such a policy would add very little to the safety of the Donors, their co-workers, or the general public, while engendering unnecessary problems and sanctions for Donors whose results would ultimately be verified as negative or canceled in any event.

s40.161: I agree with this section as written in toto, and it should be retained without further modification.

s40.171(c): I agree that the employer should be allowed to permit a test of a split specimen if the request is made later than 72 hours after the Donor has been contacted by the MRO if the employer so desires. However, I feel there should be an upper limit on this so as to permit orderly closure of this process at some reasonable point in time, and to prevent the possibility of a test failing to re-confirm due to deterioration of analytes in the specimen as a result of long storage. I suggest that the employers be permitted to allow a test of a split specimen up to 60 days after the Donor has been contacted by the MRO.

s40.183: I agree with this section as written in toto, and it should be retained without further modification. I agree that if both tests are canceled that the DER be informed that an immediate collection of another specimen under direct observation be performed.

s40.193: I agree with this section as written in toto, and it should be retained without further modification.

s40.195: The provisions of this section should be extended to all the other types of testing besides pre-employment testing. It would be in the interest of public safety if in-service employees coming up for testing who are unable to void sufficient quantities of urine who have permanent disabilities causing this have no clinical evidence of illicit drug use. Section (a)(1) should be modified to state "You will accomplish this by personally conducting, or causing to be conducted, a medical examination . . . ". As section (a)(2) properly permits the MRO to do this when he is unable to personally conduct the examination, it should be clearly stated in section (a)(1).

s40.201(c): I feel that when the Donor's signature is omitted from the certification statement, and it can not be established that this was due to refusal to sign, inability to sign (e.g. hand and arm injuries), or that the statement was in fact not signed on the Copy 4, but was on subsequent copies of the CCF, this should be a "fatal flaw", not subject to correction. By the time the MRO receives the copy of the CCF that should bear the Donor's signature at least hours, and often days have elapsed before it is realized that the signature has been omitted. As a practical matter it is often impossible to get the Donor to sign this statement at any time after he has left the collection site. Furthermore, I feel it is unfair to ask a Donor to sign this statement hours at best, but most likely days after giving the specimen, when there may no longer be any clear recollection as to exactly what transpired at the collection point, or as to whether in fact the specimen was handled properly. The MRO process can only validly proceed if the MRO has absolute confidence that the specimen he is verifying was collected, processed, handled and analyzed properly, and that the specimen really did come from the Donor in question. The Donor's signature of the certification statement is vital to me in assuring me that I am verifying the specimen actually submitted by the Donor. Attempting to get the Donor to sign the certification after leaving the collection site badly undermines this process. I strongly feel that this should be considered a "fatal flaw" not subject to correction and placed in s40.197 of this rule.

s40.301: The SAP should be permitted to obtain quantitative results of urine drug testing for Donors the SAP is working with, directly from the laboratory without MRO intermediation. Provisions should be made in this and other appropriate sections of the rule to require the laboratory to release quantitative results to the SAP provided the SAP provides a written, informed consent from the Donor permitting this. Donor's not executing such consents would of course then be considered non-cooperative and would be handled accordingly by the SAP.

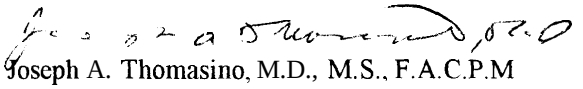
s40.307: The requirement for a minimum of six follow-up tests during the first 12 month period after a Donor's return to service is entirely adequate and appropriate. The flexibility given to the SAP to increase the number of tests, and the duration of follow-up testing ensures that in those cases where more stringent follow-up is required, rehabilitation and safety concerns will be fully addressed.

s40.329: I have grave misgivings about the provisions of this section. I am unclear as to what "personal knowledge" that a Donor with a verified positive result is also employed or seeking employment with another employer subject to a DOT agency's drug testing regulations means here. I feel these requirements are impractical in many cases, would be prone to errors of omission (intentional and more often unintentional), would be extremely burdensome in many circumstances, and would give a false sense of security on a very important issue. Some MROs, particularly those doing this as part of a general occupational health practice, may recognize or know that an employee that they have recently verified as positive is working for or seeking employment with another employer. However, in my practice, I review literally thousands of tests per month. I am certain that I would usually not be personally aware of the fact that a Donor with a verified positive result last week for one company I serve, now has a negative test for a different company that I also serve and that somehow this latter company should be informed of the prior positive result. If it could be shown on some audit, or by review of my records that this transpired and I failed to notify the latter company, am I non-compliant with the rule and subject to sanction? I maintain an electronic database of the results, does the fact that this circumstance is documented in that database constitute "personal knowledge"? Would I be required to have some sort of program to check my database for this circumstance (and if so within what time frame?) so as to "refresh" my personal

knowledge? Needless to say complying with the proposed rule as written here would be burdensome and fraught with difficulties, let alone extending that somehow to employers that the MRO does not serve (and how would the MRO ever know this?). It would seem to me that a better approach here would be to require MROs to report all verified positive results to DOT OADPC. A confidential, central registry of verified positive results could then be maintained and could be used to satisfy the valid concern that a Donor in a safety sensitive position with a positive test, dismissed from one company, does not simply continue to work for another company, or "white knuckle" (that is abstain from drugs without really addressing his dependency) for a few days, pass a new test and go to work in another safety sensitive position without addressing his drug problem. In fact, if there is real concern over this issue, and I feel there should be. such a registry makes even more sense when it is considered that is far more likely that the MRO will have no knowledge that a Donor with a verified positive is working for or attempting to work for another DOT regulated employer. Establishment of the registry would address every verified positive result and would give far greater assurance that job- hopping while still chemically dependent is not occurring.

I greatly appreciate the opportunity to provide comments concerning the proposed rule. On the whole I think that the format used is excellent and a great improvement over earlier versions of the rule. I also feel that a great many formerly untreated issues, as well as vague or gray areas of the former rule have been addressed and this will result in much better understanding of and implementation of the rule in the future. If there should be any questions concerning my comments or if further clarification should be desired, do not hesitate to contact me.

Sincerely,



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